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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,484	01/23/2002	Keith Alan Foster	1581.0870000/RWE/MTT	2134

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EXAMINER

AUDET, MAURY A

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,484

Applicant(s)

FOSTER ET AL.

Examiner

Maury Audet

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's arguments and amendment to the claims in the response of 09/21/2004 are acknowledged. Claims 1-47 are cancelled and claims 48-61 pending and examined on the merits. In order to clarify the §112 1st Scope of Enablement/§112 2nd Issues, the present action is being sent out as NON-FINAL.

35 U.S.C. § 112, 1st ¶ Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New claims 48-61 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling use of the ECL conjugate ECL- LH_N/A for a method of treating the C-fibre neuron associated diseases/conditions (Figures 3 and 13), does not reasonably provide enablement for treatment of a C-fibre neuron associated diseases/conditions with any ECL conjugate, other than ECL- LH_N/A. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally

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accepted scientific principles”, a rejection for failure to teach how to make and/or use is proper (*In re Marzocchi*, 169 USPQ 367 (CCPA 1971). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Colianni*, 195 USPQ 150, 153 (CCPA 1977), have been clarified by the Board of Patent Appeals and Interferences in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986), and are summarized in *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed.

The instant disclosure fails to meet the enablement requirement for treatment of a C-fibre neuron associated diseases/conditions with any ECL conjugate, other than ECL- LH_N/A for the following reasons:

The nature of the invention: The elected invention is drawn to the use of Erythrina cristagalli lectin (ECL) conjugate (i.e. ECL- LH_N/A) to modulate C-fibre activity in order to treat diseases or conditions resulting from inhibition or stimulation of C-fibre activity.

The amount of direction or guidance present and the presence or absence of working examples: Enablement must be provided by the specification unless it is well known in the art. *In re Buchner* 18 USPQ 2d 1331 (Fed. Cir. 1991). A search of the prior art, as to ECL conjugates for treating C-fiber related disorders, revealed a very limited number of teachings directed to the specific invention of the present application, therefore, the use of ECL conjugates for treating C-fiber related disorders cannot be construed as being well known in the art, and thus reliance for enablement must stem from the specification. The specification and claims have adequately described the use of the ECL conjugate ECL- LH_N/A in a method of treating two (2) C-fibre associated diseases or conditions: pain (i.e. analgesic affect in mouse, See Figure 3) and inflammation (pretreatment stimulated rat paw, See Figure 13). However, no other ECL

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conjugates have been described. There are no working examples to indicate whether other ECL conjugates would be enabled (and what the structure/function of these are).

The breadth of the claims and the quantity of experimentation needed: The claims are drawn broadly to the use of any ECL conjugate in methods for treating C-fibre neuron associated diseases/conditions. Absent sufficient teachings in the specification or art sufficient to overcome the teachings of unpredictability in the art as to enablement of any ECL conjugate other than ECL- LH_N/A to treat C-fibre neuron associated diseases/conditions; it would require undue experimentation by one of skill in the art to be able to practice the invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 112 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 48-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At the outset, it is noted that Applicant was required to elect a single compound, and identifying it's chemical structure, as the invention (Supplemental Restriction). This requirement still has not been met (i.e. a specific lectin, for instance, the ECL conjugate ECL- LH_N/A) and the claims thus remain indefinite as to what constitutes the elected invention. As drafted, the claimed invention is essentially unsearchable (other than the elected group) because

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the instant claims do not contain a distinguishable structure (i.e. ECL- LH_N/A) that may be searched.

Please note that the language of the claims must make it clear what subject matter the claims encompass to adequately delineate their "metes and bounds". See, e.g., the following decisions: **In re Hammack**, 427 F 2d. 1378, 1382, 166 USPQ 204, 208 (CCPA 1970); **In re Venezia** 530 F 2d. 956, 958, 189 USPQ 149, 151 (CCPA 1976); **In re Goffe**, 526 F 2d. 1393, 1397, 188 USPQ 131, 135 (CCPA 1975); **In re Watson**, 517 F 2d. 465, 477, 186 USPQ 11, 20 (CCPA 1975); **In re Knowlton** 481 F 2d. 1357, 1366, 178 USPQ 486, 492 (CCPA 1973). The courts have also indicated that before claimed subject matter can properly be compared to the prior art, it is essential to know what the claims do in fact cover. See, e.g., the following decisions: **In re Steele**, 305 F 2d. 859, 134 USPQ 292 (CCPA 1962); **In re Moore** 439 F 2d. 1232, 169 USPQ 236 (CCPA 1969); **In re Merat**, 519 F 2d. 1390, 186 USPQ 471 (CCPA 1975).

Accordingly, it is strongly suggested that the claims be amended so as to only read upon the elected invention.

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Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

MA

12/12/04



CHRISTOPHER R. TATE
PRIMARY EXAMINER